

## Environmental Protection Agency

## § 161.70

that could apply to more than a specific product, the Agency may choose to send a notice to all registrants or to publish a notice in the FEDERAL REGISTER announcing its decision. An Agency decision denying a written request to waive a data requirement shall constitute final Agency action for purposes of FIFRA section 16(a).

(d) *Availability of waiver decisions.* Agency decisions under this section granting waiver requests will be available to the public at the OPP Regulatory Public Docket located as set forth in 40 CFR 150.17(c). Any person may obtain a copy of any waiver decision by written request in the manner set forth in 40 CFR part 2.

[49 FR 42881, Oct. 24, 1984, as amended at 69 FR 39864, July 1, 2004; 71 FR 35545, June 21, 2006]

### § 161.55 Agricultural vs. non-agricultural pesticides.

Section 25(a)(1) of FIFRA instructs the Administrator to “take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and non-agricultural pesticides.” This part distinguishes the various classes of pesticide use (e.g., crop vs. non-crop) and the corresponding data necessary to support registration under FIFRA. This information is present in each data requirement table. In addition, the Use Pattern Index (appendix A) is a comprehensive list of pesticide use patterns, cross-referenced to the general use patterns appearing in the tables; the index will further assist the reader in distinguishing agricultural versus non-agricultural uses of pesticides.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

### § 161.60 Minor uses.

(a) *Minor use policy.* A minor use of a pesticide is a use on a “minor crop” (a crop which is planted on a small total amount of acreage) or a use which is otherwise limited such that the potential market volume of the product for that use is inherently small. EPA’s policy concerning data requirements for

minor uses of pesticides includes the following elements:

(1) Since the market volume for a minor use of a pesticide is intrinsically low, and the risk associated with the use often is also correspondingly low, EPA will adjust the data requirements concerning the minor use appropriately.

(2) A new data requirement pertinent to both an unregistered minor use and a registered major use will not be applied to a minor use applicant until it is applied to the major use registrations.

(3) EPA will accept extrapolations and regional data to support establishment of individual minor use tolerances.

(4) Group tolerances will be established to assist applicants for registration of products for minor uses as described in 40 CFR 180.34.

(b) *Advice on data requirements to support minor uses.* Applicants for registration are advised to contact the appropriate EPA Product Manager or the Minor Use Officer for advice on developing data to support new applications for minor uses of pesticides.

### § 161.70 Acceptable protocols.

The Agency has published Pesticide Assessment Guidelines, as indicated in § 161.20(d), which contain suggested protocols for conducting tests to develop the data required by this part.

(a) *General policy.* Any appropriate protocol may be used provided that it meets the purpose of the test standards specified in the guidelines and provides data of suitable quality and completeness as typified by the protocols cited in the guidelines. Applicants should use the test procedure which is most suitable for evaluation of the particular ingredient, mixture, or product. Accordingly, failure to follow a suggested protocol will not invalidate a test if another appropriate methodology is used.

(b) *Organization for Economic Cooperation and Development (OECD) Protocols.* Tests conducted in accordance with the requirements and recommendations of the applicable OECD protocols can be used to develop data necessary to meet the requirements specified in this part.

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Readers should note, however, that certain of the OECD recommended test standards, such as test duration and selection of test species, are less restrictive than those recommended by EPA. Therefore, when using the OECD protocols, care should be taken to observe the test standards in a manner such that the data generated by the study will satisfy the requirements of this part.

(c) *Procedures for requesting advice on protocols.* Normally, all contact between the Agency and applicants or registrants is handled by the assigned Product Manager in the Registration Division of the Office of Pesticide Programs. Accordingly, questions concerning protocols should be directed, preferably in writing, to the Product Manager responsible for the registration or application which would be affected.

### § 161.75 Requirements for additional data.

(a) *General policy.* The data routinely required by part 161 may not be sufficient to permit EPA to evaluate every pesticide product. If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed. However, EPA expects that the information required by this part will be adequate in most cases for an assessment of the properties of pesticide.

(b) *Policy on test substance.* In general, where the technical grade of the active ingredient is specified as the substance to be tested, tests may be performed using a technical grade which is substantially similar to the technical grade used in the product for which registration is sought. In addition to or in lieu of the testing required in subparts C and D of this part the Administrator will, on a case-by-case basis, require testing to be conducted with:

(1) An analytical pure grade of an active ingredient, with or without radio-active tagging.

(2) The technical grade of an active ingredient.

(3) The representative technical grade of an active ingredient.

(4) An intentionally added inert ingredient in a pesticide product.

(5) A contaminant or impurity of an active or inert ingredient.

(6) A plant or animal metabolite or degradation product of an active or inert ingredient.

(7) The end-use pesticide product.

(8) The end-use pesticide product plus any recommended vehicles and adjuvants.

(9) Any additional substance which could act as a synergist to the product for which registration is sought.

(10) Any combination of substances in paragraphs (b) (1) through (9) of this section.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

### § 161.80 Acceptability of data.

(a) *General policy.* The Agency will determine whether the data submitted to fulfill the data requirements specified in this part are acceptable. This determination will be based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the Agency will consider whether generally accepted methods were used, sufficient numbers of measurements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment. The Agency will evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible. The Agency will not reject data merely because they were derived from studies which, when initiated were in accordance with an Agency-recommended protocol, even if the Agency subsequently recommends a different protocol, as long as the data fulfill the purposes of the requirements as described in this paragraph.

(b) *Previously developed data.* The Agency will consider that data developed prior to the effective date of this part would be satisfactory to support applications provided good laboratory practices were followed, the data meet the purposes of this part, and the data